

Remarks

The September 7, 2007 Official Action has been carefully reviewed. In view of the amendments presented herewith and the following remarks, favorable reconsideration and allowance of this application are respectfully requested.

At the outset it is noted that a shortened statutory response period of three (3) months was set forth in the September 7, 2007 Official Action. Therefore, the initial due date for response is December 7, 2007.

The Examiner has objected to the specification for containing embedded hyperlinks and/or other form of browser-executable code. Applicants have amended the specification to remove the embedded hyperlinks, thereby overcoming the instant objection.

The Examiner has also objected to the specification for allegedly containing essential material incorporated by reference. Specifically, it is the Examiner's position that the sequences represented by the Unigene numbers are essential to practicing the claimed invention. Applicants respectfully disagree. 37 CFR 1.57(c) states that essential material may not be incorporated by reference when contained in a non-patent publication. However, 37 CFR 1.57(c) further defines "essential material" as "material that is necessary to ... provide a written description of the claimed invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and set forth the best mode contemplated by the inventor of carrying out the invention as required by the first paragraph of 35 U.S.C. 112." Here, it is clear that the specific sequences provided with the Unigene number are not absolutely required to make or use the instantly claimed invention. Indeed, Table S6 identifies known genes through a gene description, known biological process, and Unigene number. As such, a skilled artisan is very capable of obtaining a nucleotide sequence of

the identified genes through any source in order to make and use the instantly claimed invention. The instant invention concerns not the identification of new genes, but rather the finding that these known genes are related to the prognosis of patients with breast cancer. The recited genes in the instant claims can be readily identified by the skilled artisan through their gene description. The Unigene number provides for further confirmation or provides additional assistance to the skilled artisan for obtaining a nucleotide sequence of the recited genes. As such, the skilled artisan is readily able to identify the genes without the incorporation of specific sequences, such as those provided with the Unigene number, into the application. As such, the specific sequences themselves are nonessential material for making and using the instant invention and can, therefore, be incorporated by reference from non-patent publications (see 37 CFR 1.57(d)).

The Examiner has also objected to claims 8, 12, 22, 27, and 28 for the following four reasons. First, claim 8 has been objected to for reciting the acronym "NPI." Applicants have amended the claim to recite "Nottingham Prognostic Index (NPI)." Second, claim 12 has been objected to for omitting the article "an" prior to the term "apparatus." Applicants have amended claim 12 to recite "an apparatus." Third, the Examiner has objected to claims 22 and 28 for containing typographical errors. Applicants have corrected the typographical error in claim 22 and cancelled claim 28. Fourth, claim 27 has been objected to for omitting the term "and" prior to the final step. Applicants have added the missing word. In view of the foregoing, the objections to claims 8, 12, 22, 27, and 28 have been overcome and should be withdrawn.

The Examiner has rejected claims 28-31 under 35 U.S.C. §101 for allegedly being directed to non-statutory subject matter. Applicants have cancelled claims 28-31, thereby rendering the instant rejection moot.

Claims 1, 2, 5-11, 13-15, 17-20, 22, 24-27, 29-31,

and 33-37 have been rejected under 35 U.S.C. §112, second paragraph for alleged indefiniteness on several grounds.

Claims 1, 2, 5-11, and 27 have been rejected for allegedly failing to satisfy the enablement requirement of 35 U.S.C. §112, first paragraph.

Lastly, the Examiner has rejected claims 12, 13, 15-20, 22, and 28-37 under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent Application Publication No. 2004/0018525 (hereinafter the '525 application).

In accordance with the instant amendment, claims 15 and 28-37 have been cancelled and claims 1, 8, 12, 22, and 27 have been amended. Support for the amendment to claims 1, 8 and 27 can be found throughout the specification including, for example, pages 3, 4, 17, 18, and 29, claim 15, and Table S6. Support for the amendment to claim 12 can be found, for example, at pages 22-23. Support for the amendment to claim 22 can be found in claim 16. No new matter has been introduced into this application by reason of any of the amendments presented herewith.

The foregoing objections and rejections constitute all of the grounds set forth in the September 7, 2007 Official Action for refusing the present application.

In view of the reasons set forth in this response, Applicants respectfully submit that the objections to the specification; the objections to claims 8, 12, 22, 27, and 28; the 35 U.S.C. §101 rejection of claims 28-31; the 35 U.S.C. §112, second paragraph rejections of claims 1, 2, 5-11, 13-15, 17-20, 22, 24-27, 29-31, and 33-37; the 35 U.S.C. §112, first paragraph rejection of claims 1, 2, 5-11, and 27; and the 35 U.S.C. §102(e) rejection of claims 12, 13, 15-20, 22, and 28-37, as set forth in the September 7, 2007 Official Action, cannot be maintained. These grounds of objection and rejection are, therefore, respectfully traversed.

**CLAIMS 1, 2, 5-11, 13-15, 17-20, 22, 24-27, 29-31, AND 33-37,
AS AMENDED, SATISFY THE DEFINITENESS REQUIREMENT OF 35 U.S.C.**

§112, SECOND PARAGRAPH

Claims 1, 2, 5-11, 13-15, 17-20, 22, 24-27, 29-31, and 33-37 have been rejected under 35 U.S.C. §112, second paragraph for alleged indefiniteness on the following nine grounds.

First, the Examiner has rejected claims 1, 2, and 5-11 for allegedly omitting an essential step. It is the Examiner's position that the claims omit the step of correlating a specific result to a specific prognosis. Applicants have amended claim 1, from which claims 2 and 5-11 depend, to recite that higher levels of nucleic acid expression products of the prognostic set of genes indicates a poorer prognosis. As such, Applicants submit that the instant rejection has been overcome.

Second, the Examiner has rejected claims 2, 5-11, 24-27, and 33-37; claims 13-15,; claims 17-20 and 22; and claims 29-31 for reciting the allegedly indefinite phrases "A method according to claim," "Apparatus according to claim," "A kit according to claim," and "An expression profile accord to claim," respectively. Applicants have cancelled claims 29-37 and have amended the other claims, in accordance with the Examiner's suggestion, to recite "The method of claim," "The apparatus of claim," or "The kit of claim" instead of the allegedly indefinite phrases. Accordingly, the instant rejections have been overcome.

Third, the Examiner has rejected claims 2, 13, 14, 17, 24, and 29 for referencing a table within the specification. The Examiner states at page 10 of the instant Official Action that "reference to a table within the disclosure by a claim is not an acceptable method of claiming subject matter." Applicants respectfully disagree. Indeed, the MPEP clearly states at §2173.05(s) that reference to a specific table in a claim "is permitted only in exceptional circumstances where there is no practical way to define the

invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim." Accordingly, the MPEP clearly states that referencing a table in a claim is permissible under certain circumstances. Here, Applicants respectfully submit that it is not practical to list all 62 genes listed in Table S6 in the instantly rejected claims and that it is more concise to incorporate the table by reference rather than duplicating the table in the claim. Therefore, the reference of the table satisfies the requirements set forth by the MPEP and the instant rejection should be withdrawn.

Fourth, the Examiner has rejected claims 6 and 7 because the phrase "said expression products obtained from the sample" allegedly lacks antecedent basis. Applicants have amended claim 5, from claims 6 and 7 depend, to provide antecedent basis for the term "expression products." Accordingly, the instant rejection has been overcome.

Fifth, the Examiner has rejected claim 8 for allegedly omitting an essential step. It is the Examiner's position that the claim omits the step of correlating a specific result to a specific classification. Applicants have amended claim 8 to recite a correlation between a specific result and a specific classification. Therefore, Applicants submit that the instant rejection has been overcome.

Sixth, the Examiner has rejected claim 22 as it is allegedly unclear what the term "they" is referring to. Applicants have amended claim 22 to replace the indefinite term "they" with "nucleic acid expression products," thereby overcoming the instant rejection.

Seventh, the Examiner has rejected claim 27 for allegedly omitting an essential step. It is the Examiner's position that the claim omits the step of correlating a specific result to a particular prognosis. Applicants have amended claim 27 to recite a correlation between a specific result and a specific prognosis, thereby overcoming the instant rejection.

Eighth, the Examiner asserts there is insufficient antecedent basis for the phrase "the source tumour" in claim 31. Applicants have cancelled this claim, thereby rendering the instant rejection moot.

Lastly, the Examiner contends that claim 36 omits an essential step. Applicants have cancelled this claim, thereby rendering the instant rejection moot.

In view of the foregoing, the rejections of claims 1, 2, 5-11, 13-15, 17-20, 22, 24-27, 29-31, and 33-37 under 35 U.S.C. §112, second paragraph for alleged indefiniteness cannot be reasonably maintained. Withdrawal of the rejections is respectfully requested.

CLAIMS 1, 2, 5-11, AND 27, AS AMENDED, SATISFY THE ENABLEMENT REQUIREMENT OF 35 U.S.C. §112, FIRST PARAGRAPH

Claims 1, 2, 5-11, and 27 have been rejected for allegedly failing to satisfy the enablement requirement of 35 U.S.C. §112, first paragraph. It is the Examiner's position that while the specification is enabling for a "method of determining the prognosis of a first patient with breast cancer comprising comparing the polynucleotide expression levels of a set of genes comprising adenine phosphoribosyltransferase, MCM4 minichromosome maintenance deficient 4 (*S. cerevisiae*), exonuclease 1, Metallothionein 1H-like protein, and clone IMAGE: 5270727 in a breast tumor sample from said first patient to the expression levels of the polynucleotides of said set of genes in a breast tumor sample from a second patient, wherein a first patient with higher levels of expression of polynucleotides of said set of genes has a poorer prognosis than a second patient with lower levels of expression of said set of genes," the specification allegedly does not reasonably enable a method based on any expression level of the set of genes determined by any method.

Applicants respectfully disagree with the Examiner's position and submit that the claims are fully enabled as previously presented. However, in the sole interest of

expediting prosecution, Applicants have amended the claims to recite nucleic acid expression products, which the Examiner acknowledges as being fully enabled, thereby overcoming the instant rejection. Withdrawal of the enablement rejection is respectfully requested.

**CLAIMS 12, 13, 15-20, 22, and 28-37, AS AMENDED, ARE NOT
ANTICIPATED BY THE '525 APPLICATION**

The Examiner has rejected claims 12, 13, 15-20, 22, and 28-37 under 35 U.S.C. §102(e) as allegedly anticipated by the '525 application. It is the Examiner's position that the '525 application teaches a "prognostic set for determining the prognosis of a patient with breast cancer" and discloses the Affymetrix U133 apparatus which comprises a "nucleic acid microarray wherein the binding members are nucleic acid sequences designed to detect polynucleotide expression of tens of thousands of genes."

Applicants respectfully disagree with the Examiner's position. However, in the sole interest of expediting prosecution of the instant application, Applicants have amended claim 12, from which claims 13 and 15-20 depend, to recite that the solid support houses binding members to no more than 500 different genes. As stated by the Examiner at page 25 of the instant Official Action, the '525 application describes a support which houses binding members to tens of thousands of genes. Indeed, paragraph [0487] of the '525 application states that the arrays each comprise approximately 40,000 transcripts.

It is a well settled premise that in order to constitute evidence of lack of novelty under 35 U.S.C. §102, a prior art reference must identically disclose each and every element of the rejected claim. In re Bond, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). Inasmuch as the '525 application fails to teach, or even suggest, a solid support housing nucleic acid binding members for not more than 500 different genes **and** housing nucleic acid binding members capable of specifically

and independently binding to an expression product of one of a prognostic set of genes including adenine phosphoribosyltransferase, MCM4 minichromosome maintenance deficient 4 (*S. cerevisiae*), exonuclease 1, Metallothionein 1H-like protein, and clone IMAGE: 5270727, the '525 fails to disclose each and every element of the instantly claimed invention.

With regard to claim 22, Applicants note that the claim, as amended, recites a kit comprising a plurality of nucleic acid binding members capable of specifically binding to nucleic acid expression products of genes of a prognostic set of genes and a detection reagent, wherein the prognostic set includes adenine phosphoribosyltransferase, MCM4 minichromosome maintenance deficient 4 (*S. cerevisiae*), exonuclease 1, Metallothionein 1H-like protein, and clone IMAGE: 5270727, and wherein the nucleic acid binding members are PCR primers for the nucleic acid expression products of the genes of the prognostic set. The '525 application clearly fails to teach kits comprising such PCR primers. Accordingly, it is evident that the '525 application fails to teach each and every feature of the instantly claimed kit.

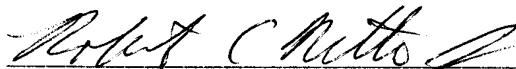
In view of the foregoing and the cancellation of claims 28-37, Applicants respectfully submit that the rejection of claims 12, 13, 15-20, 22, and 28-37 cannot be reasonably maintained and should be withdrawn.

CONCLUSION

In view of the remarks presented herewith, it is respectfully urged that the objections and rejections set forth in the September 7, 2007 Official Action be withdrawn and that this application be passed to issue.

In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any outstanding issues may be resolved through a telephone interview, the Examiner is requested to telephone the undersigned at the phone number given below.

Respectfully submitted,
DANN, DORFMAN, HERRELL AND SKILLMAN
A Professional Corporation

By 
Robert C. Netter, Jr., Ph.D., J.D.
PTO Registration No. 56,422

Telephone: (215) 563-4100
Facsimile: (215) 563-4044